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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,684	04/16/2004	Reinerus G. Gieling	SYN-0038	8864

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EXAMINER	
JAISLE, CECILIA M	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,684	GIELING ET AL.	
	Examiner	Art Unit	
	Cecilia M. Jaisle	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4-16-04, 8-25-04 & 12-8-04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-8-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-22 are rejected under 35 USC 103 over Kennis, et al., U.S. Pat. No. 4,804,663, patented February 14, 1989 [hereinafter, Kennis].

Kennis describes and claims 3-piperdinyl-substituted 1,2-benzisoxazoles, including the compound risperidone, 3-[2-[4-(6-fluoro-1,2-benzioxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one, and its pharmaceutically acceptable acid addition salts, including specifically the hydrochloride and other salts (col. 1, line 23-col. 2, line 55 and col. 7, line 57-col. 8, line 4, and claims 1-6, *inter alia*). Kennis teaches and claims pharmaceutical compositions with effective amounts such as between about 0.01 – 4 mg/kg of body weight of the subject (col. 10, lines 27-40, and claims 7-12, *inter alia*) and the compositions may include a pharmaceutically acceptable excipient (col. 9, line 33-col. 10, line 11, and claims 7-12, *inter alia*). Kennis notes, "Acid addition salts of (I) due to their increased water solubility over the corresponding base form, are obviously more suitable in the preparation of

aqueous compositions" (col. 10, lines 7-11). The salts are prepared by contacting risperidone with a therapeutically active non-toxic acid, such as hydrochloric, methanesulfonic, benzenesulfonic, acetic, 2,3-dihydroxybutanedioic (i.e., tartaric), hydroxybutanedioic (i.e., malic), (z)-butenedioic (i.e., maleic), 2-hydroxypropanoic (i.e., lactic), etc. (col. 7, line 57-col. 8, line 4). Kennis describes and claims methods of treating mammalian psychotic disorders with risperidone salts (col. 9, line 11-col. 10, line 40, and claims 13-18, *inter alia*).

The instant claims differ from Kennis by reciting specific salt forms of risperidone, while Kennis teaches acid salts broadly. One of ordinary skill in the art would have been motivated to prepare specific salt forms of risperidone, because Kennis generically shows such salt forms, their method of preparation and their increased water solubility. The skilled artisan would have had a reasonable expectation that these salt forms would also exemplify the same pharmaceutical activity as the Kennis compounds. In regard to the present claims' obviousness, it would be well within the skill of the ordinary organic chemist to form mono- or di-salts of risperidone by selecting appropriate stoichiometric quantities of the base and the acid, to isolate and purify the crystalline salt form, or to carry out the salt formation in a suitable solvent, such as water or ethanol, because Kennis mentions these solvents as compatible with risperidone (col., 9, line 33-col. 10, line 11, *inter alia*). Determining the appropriate dosage from the Kennis teachings would be well within the skill of the ordinary pharmaceutical chemist. The skilled organic chemist and the skilled pharmaceutical chemist would be well motivated to

make these modifications in order to prepare compounds for their pharmaceutical use.

Claims 1, 3, 4, 7-13 and 21 are rejected under 35 USC 103 over Mesens, et al., U.S. Pat. No. 5,612,346, patented March 18, 1997 [hereinafter, Mesens].

Mesens describes and claims risperidone pamoate, antipsychotic compositions and methods of treating warm-blooded animals suffering from psychotic diseases (col. 1, line 31-col. 3, line 53 and claims 1-7, *inter alia*), in which effective amounts of risperidone pamoate are, e.g., between about 0.05–50 mg/kg body weight (col. 3, lines 42-53, *inter alia*), and the compositions may include pharmaceutically acceptable excipients (col. 2, line 66-col. 3, line 38, *inter alia*). The salt is prepared by contacting risperidone with pamoic acid (col. 1. line 55-col. 2, line 3 and Example 1, *inter alia*).

The instant claims differ from Mesens by reciting specific salt forms of risperidone, while Mesens teaches risperidone pamoate salts broadly. One of ordinary skill in the art would have been motivated to prepare specific pamoate salt forms of risperidone, because Mesens generically shows such salt forms, their method of preparation and their increased water solubility. The skilled artisan would have a reasonable expectation that these pamoate salt forms would also exemplify the anti-psychotic properties described by Mesens for risperidone pamoate. Further in regard to the obviousness of the present claims, it would be well within the skill of the ordinary organic chemist to isolate and purify the crystalline pamoate salt form. It would be well within the skill of the ordinary pharmaceutical chemist to determine the appropriate

dosage from the teachings of Mesens. The skilled organic chemist and the skilled pharmaceutical chemist would be well motivated to make these modifications in order to prepare compounds for their pharmaceutical use.

Obvious Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 1-33 of copending Ser. No. 10/825,684 by Gieling, et al., entitled to the filing date of a provisional application April 22, 2003 [hereinafter, Gieling]. Gieling claims certain hydrochloride salts of risperidone, a method of making them, pharmaceutical compositions and method for

treating mammalian psychotic disorders using these risperidone hydrochloride salts. The claims of the present application, directed specifically to certain salts of risperidone, methods of making them, pharmaceutical compositions and methods for treating mammalian psychotic disorders using these risperidone salts, overlap the Gieling claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-22 are pending and rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia Jaisle, J.D.

DEEPAK RAO
PRIMARY EXAMINER